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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,866	02/20/2004	Kinneret Savitzky	2786-0245P	5161

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BOSTON, MA 02111

EXAMINER
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DANG, IAN D

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/781,866

Applicant(s)

SAVITZKY ET AL.

Examiner

Ian Dang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-76 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-76 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, 5, and 9-11 drawn to an isolated nucleic acid sequence of an alternative splicing variants, and expression vector and host cell classified in class 536, subclass 23.1.
- II. Claims 3 and 4 drawn to an amino acid sequence, classified in class 530, subclass 300.
- III. Claims 6-8 drawn to a purified antibody binding specifically to any of the amino acid sequence of claim 3 or 4, classified in class 424, subclass 130.1.
- IV. Claims 12-15, drawn to a pharmaceutical composition for treatment of diseases which can be ameliorated or cured by raising the level of an amino acid, classified in class 514, subclass 12.
- V. Claim 16, drawn to a method for detecting a variant nucleic acid sequence in a biological sample, classified in class 435, subclass 6.
- VI. Claims 17-21, drawn to a method for determining the level of variant nucleic acid sequences in a biological sample, classified in class 436, subclass 6.
- VII. Claims 22-24, drawn to a method for identifying candidate compounds capable of binding to the variant product modulating its activity, classified in class 435, subclass 7.2.
- VIII. Claim 25, drawn to an activator of an amino acid sequence, classified in class 435, subclass 7.2.

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- IX. Claim 26, drawn to a deactivator of an amino acid sequence, classified in class 435, subclass 7.2.
- X. Claims 27-30, drawn to a method for detecting an amino acid sequences in a biological sample, classified in class 435, subclass 7.1.
- XI. Claims 31-32, 35, 38-43, and 45-47, 50-51, and 76 drawn to an isolated nucleic acid sequence, classified in class 536, subclass 23.1.
- XII. Claims 33-34, 44 and 48-49 drawn to an amino acid sequence encoded by the isolated nucleic acid sequence, classified in class 530, subclass 300.
- XIII. Claim 36 drawn to a purified antibody binding an amino acid sequence, classified in class 424, subclass 130.1.
- XIV. Claim 37, drawn to a purified antibody binding an alternative splice variant of an amino acid sequence, classified in class 424, subclass 130.1.
- XV. Claims 52, 55-57 58, 59, 60, 65, and 66 drawn to a method for detecting a variant nucleic acid sequence in a biological sample, classified in class 435, subclass 6.
- XVI. Claim 53, 61, 62, 63, 72 drawn to a method for determining the level of variant nucleic acid sequence in a biological sample, classified in class 435, subclass 6.
- XVII. Claim 54, drawn to a method for determining the ratio between the level of variant of the nucleic acid sequence in a first biological sample and the level of the original sequence from which the variant has been varied by alternative splicing in a second biological sample, classified in class 435, subclass 6.
- XVIII. Claim 64, drawn to a method of identifying candidate compounds capable of binding to the variant product and modulating its activity, classified in class 435, subclass 7.2.

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- XIX. Claim 67, drawn to an activator of an amino acid sequence, classified in class 435, subclass 7.8.
- XX. Claim 68, drawn to a deactivator of an amino acid, classified in class 435, subclass 7.8.
- XXI. Claims 69-71, drawn to a method for detecting and determining the amino acid sequence in a biological sample, classified in class 435, subclass 7.1.
- XXII. Claims 73-75, drawn to an expression vector and host cell, classified in class 435, subclass 320.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different starting materials, methods steps, and/or goals. Thus the methods and products are exclusive and require non-cohesive searches and considerations.

**If Group I, III, V, or VI is elected then election is also required of one SEQ ID NO among SEQ ID NO:1 to SEQ ID NO:26. Please note: This is a further restriction requirement. It is not an election of species.**

**If Group II, IV, VII, VIII, IX, or X are elected then election is also required of one SEQ ID NO among SEQ ID NO:27 to SEQ ID NO:52. Please note: This is a further restriction requirement. It is not an election of species.**

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02) and have acquired a separate status in the art because of their recognized divergent subject matter and the

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necessity of non-coextensive non-patent literature searches, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


### Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ian Dang whose telephone number is (571) 272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
September 14, 2006

  
**BRENDA BRUMBACK**  
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